

Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 9, 23-26, 28, 35 and 36 are rejected for lack of written description. Applicants respectfully request reconsideration and withdrawal of the rejection.

The present specification provides sufficient written description to support claims 9, 23-26, 28, 35 and 36. For example, on pages 51 and 52 the individual domains that can be added or deleted are described by their specific location in SEQ ID NO:2, as well as by function. Having set forth the specific amino acid sequences of these fragments in SEQ ID NO:2, nothing more is needed to describe these sequences, so that one of skill in the art would know that the present Applicants had possession of the entire sequence of SEQ ID NO: 2 and knew where the specific domains were located as well as the function of each domain. The specification adequately describes these fragments. Therefore, claims 9, 23-26, 28, 35 and 36 comply with the requirements for written description under 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 U.S.C. § 101

Claims 2-5, 9, and 23-27 are rejected by the examiner under 35 U.S.C. § 101 for allegedly not being supported by either a credible, specific and substantial asserted utility, or a well established utility. Applicants respectfully request reconsideration and withdrawal of the rejection.

Attached herewith are Jörnvall, H. et al. *JBC* **276** 5140-5146 (2001) and Sebolt-Leopold, J.S. *Oncogene* **19** 6594-6599 (2000), appendices 1 and 2, respectively. The teachings of these documents support an approach for medical therapies targeting ALK7 that are useful for treating cancer. This utility is supported by the present specification, which discusses that inhibitors or modulators of ALK7 can have therapeutic value in the treatment of proliferative diseases such as cancer. See pages 30-32. On page 5146 of Jörnvall (left panel), ALK7's involvement in MAP kinase activation is discussed. Sebolt-Leopold states that the MAP kinase pathway encompasses a cascade of phosphorylation events (involving Raf, MEK and ERK) which presents novel opportunities for the development of new cancer

therapies. See Sebolt-Leopold abstract. Additionally, on page 6597, left panel of Sebolt-Leopold, it states “Of the numerous therapeutic approaches to cancer treatment, most take the form of a single-pronged attack aimed at either : (1) slowing of tumor growth, (2) inhibition of invasion and metastasis, (3) induction of tumor cell death, or (4) promotion of tumor differentiation. However, by pharmacological intervention of the MAP kinase pathway, one can envision a single agent that concurrently exploits more than one of these processes.” Sebolt-Leopold describes data obtained with MEK inhibitors as an illustrative example. Since ALK7 activates the MAP kinase pathway, and the MAP kinase pathway has been identified as a target for cancer treatment, it can be concluded that medical therapies targeting ALK7 provide an approach for treating cancer. Therefore, the present claims are supported by a credible, specific and substantial asserted utility, as well as a well established utility.

Additionally, on page 90 of the present specification, the results of experiments detecting the expression of ALK7 in adult human tissues are reported. Since a significant amount of ALK7 RNA was detected in the lung, medical therapies targeting ALK7 may be useful for treating lung cancer.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 2-5, 9, and 23-27 are rejected by the examiner under 35 U.S.C. § 112, second paragraph, for lack of enablement. The examiner asserts that since the invention is allegedly not supported by either a credible, specific and substantial asserted utility, or a well established utility, a person of ordinary skill in the art would not know how to use the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

As discussed above, the teachings of Jörnvall and Sebolt-Leopold establish that that medical therapies targeting ALK7 are likely to be useful for treating cancer. Therefore, since the present invention possesses a credible, specific and substantial asserted utility, as well as a well established utility, a person of ordinary skill in the art would know how to use the claimed invention.

CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

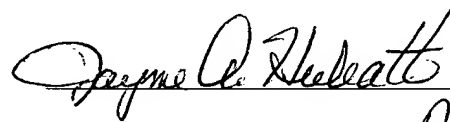
If the examiner has any questions concerning this application, he or she is requested to contact the undersigned.

Respectfully submitted,

Date March 11, 2002

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